

510(K) SUMMARY

A. Submitter Information

Manufacturer:

Medos International Sàrl
Chemin-Blanc 38
2400 Le Locle, Switzerland

Submitter:

DePuy Spine, Inc.
325 Paramount Drive
Raynham, MA 02767

Contact Person:

Kirsten Lehmuller
325 Paramount Drive
Raynham, MA 02767

Telephone number:

508-828-3291

Fax number:

508-828-3797

Email:

klehmull@its.jnj.com

SEP 12 2013

B. Date Prepared

June 18, 2013

C. Device Name

Trade/Proprietary Name:

EXEDIUM® Spine System, VIPER and VIPER2 Systems

Common/Usual Name:

Spinal System

Classification Name:

Spinal interlaminar fixation orthosis
per 21 CFR §888.3050 - KWP
Spinal intervertebral body fixation orthosis
per 21 CFR §888.3060 - KWQ
Pedicle screw spinal fixation
per 21 CFR §888.3070 - NKB, OSH, MNH, MNI

D. Predicate Device Name

Trade name: EXPEDIUM® Anterior Spine System (K041205)
EXPEDIUM® Spine System (K101993)
EXPEDIUM® and VIPER® and VIPER®2 Spine Systems (K111136)

E. Device Description

The EXPEDIUM® and VIPER® and VIPER®2 Spine Systems consist of titanium rods, pedicle screws, connectors, hooks, and extended tab implants, which are terminally sterilized via gamma radiation. Previously, these devices were commercialized as clean, non-sterile, and the end-user would need to sterilize the units prior to use via steam sterilization. Certain implants will be packaged in sterile multi-packs for customer convenience.

F. Intended Use

The EXPEDIUM, VIPER, and VIPER2 Spine Systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.

The EXPEDIUM, VIPER, and VIPER2 Spine System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor, pseudoarthrosis; and failed previous fusion in skeletally mature patients.

When used in a posterior percutaneous approach with MIS instrumentation, the VIPER System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor, pseudoarthrosis; and failed previous fusion in skeletally mature patients.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the EXPEDIUM and VIPER/VIPER2 System metallic implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The EXPEDIUM and VIPER/VIPER2 systems

are intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

F. Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use

The proposed modifications to the EXPEDIUM, VIPER and VIPER2 Systems are identical to the predicate devices (K111136) except for the proposed devices will be terminally sterilized via gamma radiation. The design, materials, indications, and technology remain identical to the predicate systems.

G. Materials

Manufactured from ASTM F-136 implant grade titanium alloy and ASTM F-562 Cobalt-28 Chromium-6 Molybdenum Alloy.

H. Performance Data

Performance data is not provided in this submission.

I. Conclusion

The Substantial Equivalence Justification demonstrate that the devices are as safe, as effective, and perform as well as the predicate devices.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 12, 2013

Medos International Srl
% Ms. Kirsten Lehmuller
Regulatory Affairs Associate
DePuy Spine, Incorporated
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K131802

Trade/Device Name: EXEDIUM[®] Spine System, VIPER and VIPER2 Systems
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, KWP, KWQ, MNH, MNI
Dated: August 20, 2013
Received: August 21, 2013

Dear Ms. Lehmuller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Erin D. Keith

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K131802

Device Name: EXPEDIUM® Spine System, VIPER and VIPER2 Systems

Indications For Use:

The EXPEDIUM, VIPER, and VIPER2 Spine Systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.

The EXPEDIUM, VIPER, and VIPER2 Spine System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor, pseudoarthrosis; and failed previous fusion in skeletally mature patients.

When used in a posterior percutaneous approach with MIS instrumentation, the VIPER System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor, pseudoarthrosis; and failed previous fusion in skeletally mature patients.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the EXPEDIUM and VIPER/VIPER2 System metallic implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The EXPEDIUM and VIPER/VIPER2 systems are intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Prescription Use ☒ X ☐

AND/OR

Over-The-Counter Use ☐ ☐

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)

Division of Orthopedic Devices

510(k) Number: K131802